

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Investigating the effect of tranexamic acid with gelfoam carrier in preventing dry cavity syndrome following surgical extraction of impacted mandibular third molar.

Protocol summary

Study aim

The effectiveness of the use of Tranexamic acid with Gelfoam carrier to prevent the occurrence of dry cavity syndrome following mandibular third molar surgery.

Design

Single group clinical trial with case and control in one person in split mouth, single blind, randomized, phase 3 on 72 patients. The randomization tool is a sealed envelope with a random sequence

Settings and conduct

This study is a clinical research and a randomized controlled trial. Research data are collected from clinical trial findings in patients referred to maxillofacial surgery department of Azad Islamic Faculty of Dentistry in Tehran in academic year 1401-1402. Tranexamic acid drug used in surgery is 250 mg capsule powder. On the intervention side, the area is washed and the cavity is filled with gelfoam impregnated with tranexamic acid capsule powder and sutured, and then a sterile gauze is placed in the area for half an hour. On the control side, a sterile gauze is placed in place without using any local coagulant. Blinding is a bias and assessor.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18 and 35 years, lower mandibular third molar teeth, bilaterally, Exclusion criteria: blood diseases such as anemia, thalassemia, hemophilia, and corticosteroid use.

Intervention groups

All patients undergo wisdom tooth extraction surgery by one person. The tranexamic acid drug used in surgery is in the form of 250 mg capsule powder. On the side of the intervention, the area is washed and the cavity is filled with Gelfoam impregnated with tranexamic acid capsule powder and sutured, and then a sterile gauze is placed in the area for half an hour. It will be given. On the control side, a sterile gauze is placed in place without using any local coagulant

Main outcome variables

Occurrence of dry socket phenomenon

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230604058381N1**

Registration date: **2023-06-24, 1402/04/03**

Registration timing: **prospective**

Last update: **2023-06-24, 1402/04/03**

Update count: **0**

Registration date

2023-06-24, 1402/04/03

Registrant information

Name

Misagh mohajer

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3626 0423

Email address

m_mohajer@ymail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-26, 1402/04/05

Expected recruitment end date

2023-07-27, 1402/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the effect of tranexamic acid with gelfoam carrier in preventing dry cavity syndrome following surgical extraction of impacted mandibular third molar.

Public title
Investigating the effect of tranexamic acid with gelfoam carrier in preventing dry cavity syndrome

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
age between 18 and 35 years the impacted third molars of the mandible bilateral placed in class I, II and III, level A, B and C based on the classification of Paul and Gary Gouri eed to remove the tooth surgically
Exclusion criteria:
Users of exogenous contortionists the presence of systemic disorders respiratory and digestive diseases pregnant women and lactating mothers systemic fungal infections acute infections and active or silent tuberculosis

Age
From **18 years** old to **35 years** old

Gender
Both

Phase
3

Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **72**
More than 1 sample in each individual
Number of samples in each individual: **2**
The research is split mouth and on one side of the patient's jaw an intervention (transamic acid drug) is used along with a foam gel carrier and on the other side no drug is used and it is left without intervention.

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we used the restricted randomization method randomization (block randomization type) We will use randomization. Blocking is usually used in order to Creating a balance in the number of samples assigned to each of the groups be used for study. This feature helps researchers to Cases that require intermediate analyzes during the sampling process be the number of samples assigned to each of the case groups The study is equal. The size of all the blocks is equal and we are in this Single-group trial of 4 blocks (including 4 participants in We will have an intervention group and a control). The randomization tool is also from sequence generation software Random (random software allocation) is used that this Random sequence generation software is capable of simple randomization They are used to generate random sequences using the block

method. To hide We use Concealment Allocation We use the method used to execute the sequence Randomization is applied to the participants in the study, in a way Before assigning the individual, the assigned group is not clear. With from sealed opaque envelopes with random sequence (envelopes opaque, sealed, numbered Sequentially (which in In this method, each random sequence is created on a card It is registered and the cards are placed in the envelopes in order become In order to preserve the random sequence on the outer surface of the envelope Numbering is done in the same order. Finally, the envelope door The letters are glued and placed in a box in order. At The time of starting the registration of participants, based on the order of entry of the company Eligible candidates to study, one of the letter envelopes in open order and the assigned group of that participant is revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluator does not know the type of intervention and the study is conducted in a single blind manner

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Dentistry Faculty - Islamic Azad University of Medical Sciences, Tehran

Street address

No. 9, Pasdaran St., Nistan 9th

City

Tehran

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Tehran

Postal code

1946853314

Approval date

2022-12-05, 1401/09/14

Ethics committee reference number

IR.IAU.DENTAL.REC.1401.098

Health conditions studied

1

Description of health condition studied

dry socket

ICD-10 code

M27

ICD-10 code description

Primary outcomes

1

Description

Occurrence or absence of dry socket syndrome

Timepoint

Two or three days after surgery on both intervention and control sides

Method of measurement

Evaluation through clinical observation by maxillofacial surgeon

Secondary outcomes

empty

Intervention groups

1

Description

All patients undergo wisdom tooth extraction surgery by one person. The type of cut in all operations is similar and buccal flap type with distobuccal releasing, along with sulcular cut to the mesial of tooth seven. After giving anesthesia, making the cut, and setting aside the flap, some of the bone covering the tooth will be removed with a surgical burr, and after sectioning the tooth and removing it, on the side of the intervention, wash the area and the cavity with Gelfoam impregnated with tranexamic acid 250 capsule powder. The milligram of Amin Pharmaceutical Company is filled, then it is sutured using 0.3 chromic thread and a 26 mm needle, and then a sterile gauze is placed in the area for half an hour. For better control and elimination of the effect of infection, amoxicillin 250 mg capsules will be prescribed every 8 hours for all patients, and Gelofen 500 mg tablets will be prescribed every 6 hours for possible pain control. The patient is asked to do the following in the first 24 to 48 hours: 1- Use cold and liquid foods such as: cold milk, cold soup, cold fruit juice, ice cream, etc. 2- Never hot foods and or do not consume chewing gum. 3- Avoid brushing the area of the extracted tooth. 4- Avoid smoking and do not spit out your saliva in any way. 5- Avoid stimulating the area of the extracted tooth with hand or tongue. 6- Avoid heavy sports and physical work and give priority to rest. • After one day of surgery, normal saline solution at least five times a day for one It should be used as a mouthwash for a week. Two or three days after the extraction of the impacted third molar tooth, the visit time for the clinical examination of the dry cavity or the absence of a dry cavity is determined for the patient, and the examination is performed by another maxillofacial surgeon and the symptoms of the posterior cavity Clinical examination will be recorded

Category

Prevention

2

Description

Control group: Control group: On the control side, all the patients were subjected to surgery to remove the mandibular wisdom teeth by one person. The type of cut in all operations is similar and buccal flap type with distobuccal releasing, along with sulcular cut to the mesial of tooth seven. After giving anesthesia, making the incision, and setting aside the flap, some of the bone covering the tooth will be removed with a surgical burr, and after sectioning the tooth and removing it, on the control side of the washing area and the cavity without using any local coagulant with Using a 0.3 chromic thread and a 26 mm needle, stitches are made, and then a sterile gauze is placed in the area for half an hour. For better control and elimination of the effect of infection, amoxicillin 250 mg capsules will be prescribed every 8 hours for all patients, and Gelofen 500 mg tablets will be prescribed every 6 hours for possible pain control. The patient is asked to do the following in the first 24 to 48 hours: 1- Use cold and liquid food such as: cold milk, cold soup, cold fruit juice, ice cream, etc. 2- Do not eat hot or chewy food in any way. 3- Avoid brushing the area of the extracted tooth. 4- Avoid smoking and do not spit out your saliva in any way. 5- Avoid stimulating the area of the extracted tooth with hand or tongue. 6- Avoid heavy sports and physical work and give priority to rest. • After one day of surgery, normal saline solution at least five times a day for one It should be used as a mouthwash for a week. Two or three days after the extraction of the impacted third molar tooth, the visit time for the clinical examination of the dry cavity or the absence of a dry cavity is determined for the patient, and the examination is performed by another maxillofacial surgeon and the symptoms of the posterior cavity Clinical examination will be recorded

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Islamic Azad University of Medical Sciences - Faculty of Dentistry, Tehran branch

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Hassan Mesgari

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available